

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 15-20 and 27-37 are in the case.

### **I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Ms. Robinson) for kindly agreeing to conduct an interview in this case. The interview was held on March 8, 2011 and the courtesies extended by the Examiner were most appreciated. The substance of the interview will be clear from the Interview Summary and the comments presented below.

### **II. CLAIM OBJECTIONS**

Claim 15 is objected to because items (a) and (c) recite "a host cell/the host cell", whereas item (b) recites "host cells". In response, the claim language has been amended to be internally consistent. In addition, the claim has been amended to change "the host cell's genome" to read "the host cell genome".

Claim 29 is objected to for the recitation of "a modified host cell" in the preamble and "host cells" in the method steps. In response, claim 29 has been amended to be consistent. Withdrawal of the claim objections is respectfully requested.

### **III. THE FORMAL REJECTION**

Claims 15-20 and 27-38 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because claims 15 and 29 as amended recite, "transfecting a

host cell with an expression cassette which is covalently coupled to a fluorescent label", whereas the specification [0041-0042] discloses plasmid pGBDEL4L as containing an expression cassette to drive expression. In response, the claims have been amended to refer to transfecting a host cell with a plasmid containing an expression cassette where the plasmid is labeled with a fluorescent label. Support appears in Example 4.

Claim 16 is rejected as allegedly indefinite for the recitation of the DNA being "involved" in production of the desired metabolite. In response, as suggested by the Examiner during the interview, claim 16 has been amended to state that the expression cassette "produces" the desired metabolite.

Claim 28 is rejected as allegedly indefinite for reciting that the RNA and protein expression levels are "altered" in the modified host cell. In response, claim 28 has been amended to state that the RNA and protein expression levels in the modified host cell are different to the RNA and protein expression levels in the non-modified host cell.

Claims 30 and 35 are indefinite for the recitation of "under proliferating conditions" because neither the claims nor the specification sets forth what those conditions are. In response, the claims have been amended to state that the transfected host cells are cultured between their separation and isolation under conditions to allow protein expression. Claim 16 has similar language.

Claim 20 is indefinite for the recitation of an "anti-infective". In response, this expression has been canceled without prejudice.

No new matter is entered. Withdrawal of the formal rejection is respectfully requested.

#### IV. THE ANTICIPATION REJECTIONS

Claims 15-18, 28-30, 33-35 and 37 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wolff *et al.* (U.S. Patent No. 6,262,252, July 17, 2001) (Wolff). Claims 15-18, 28-30, 33-35 and 37-38 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Johnson *et al.* (AAPS Pharmsci, 1999, cited on the IDS filed January 18, 2007) (Johnson). The rejections are respectfully traversed.

As claimed, there is provided a method for preparation of a modified host cell. The method comprises (a) transfecting a host cell with a plasmid containing an expression cassette where the plasmid is labeled with a fluorescent label that provides a non-inheritable trait to the host cell, (b) isolating the transfected host cell by detecting the fluorescent label and then separating fluorescent host cells which were transfected from non-fluorescent host cells which were not transfected, (c) culturing the transfected host cell such that fluorescently-labeled polynucleotide integrates into the host cell genome, (d) multiplying the transfected host cell which has polynucleotide integrated into the genome to dilute the fluorescent label and lose the label in the transfected host cell progeny, and (e) isolating from non-labeled progeny of the transfected host cell a modified host cell having a changed metabolic property as compared to the host cell prior to transfection.

As discussed during the interview, and as reflected in the Interview Summary, the claimed method requires transfection of a host cell with an expression cassette to provide a modified host cell having a changed metabolic property as compared to the host cell prior to transfection. Neither Wolff nor Johnson describes integration of a fluorescently-labeled **expression cassette** thereby changing a metabolic property of

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transfected host cells, as required by the claimed invention. Withdrawal of the anticipation rejections is respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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